

Webinar and TA Questions Outstanding

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Chemicals

Guidance to consider:

<https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations>

<https://www.hse.gov.uk/brexit/chemicals-brexit-guidance.htm>

Questions

Regarding: 'UK Downstream users (who do not hold an EU REACH registration) currently importing chemicals from an EU/EEA country need to ensure the substance they purchase are covered by a valid UK REACH Registration.' presuming that the obligations apply to articles and mixtures

imported into GB or is it just pure substances? And does the amount of any single substance imported need to exceed 1 tonne per annum? Or does the requirement apply to all downstream users?

UK REACH will apply to substances, either on their own, in mixtures or articles in quantities of a tonne or more.

Under EU regulation a distributor is not a downstream user, is this also the case with UK REACH i.e. it's the company/person using the substance? E.g. GB hospital pathology labs, GP practices using Near Patient Tests etc., Diabetics using Self-Test glucose meters? (or not if they are using less than 1 tonne per year?).

The definition of a downstream user will remain the same under UK REACH as it is currently under the EU equivalent.

'Downstream users are users of chemicals under UK REACH. They are companies or individuals: within Great Britain, who use a substance, either on its own or in a mixture, in their industrial or professional activities.'

is it the importer that will have to complete a DUIN notification or the downstream user?, and if goods are ordered and shipped direct from Europe to the end user does the end user (the downstream user) become the importer?

Under UK REACH, the responsibility to register a substance falls on manufacturers or importers of a substance into the GB market. As a result, those individuals currently acting as downstream users of chemicals imported from the EU/EEA will become importers after the end of the TP. It is this group who are able to submit DUINs.

Or are finished IVDs exempt? Or only if used directly by the patient rather than a professional user?

Finished IVD's are exempt.

Under EU regulation the importer into the EU has to meet the importer requirements. Is this the same under UK REACH i.e. a distributor may find that they are now the importer into GB, and subject to importer obligations separate from DUIN?

The importer requirements will remain the same under UK REACH as it is currently under the EU equivalent.

'A new registration must be submitted to the HSE within 2,4, or 6 years' – I understand that the 6 year date is based on importing > 1 tonne per year. What are the obligations of distributors/importers bringing in less than 1 tonne per year?

The deadline for submission of a full registration following submission of basic information to support the grandfathering process or a DUIN is dependent on tonnage band and hazard classification. There are no registration obligations for substances being imported or manufactured in GB in volumes of a tonne or less.

‘UK Downstream user can encourage their EU/EEA supplier to appoint a UK based Only Representative’. I understand that If an EU/EEA Supplier is not the manufacturer they cannot appoint a UK based OR (Ordinary Representative) as this has to be directly mandated by the manufacturer of the substance, is this correct?

UK REACH will adopt the same approach to the appointment of Only Representatives as is currently in place under EU REACH. This means that ORs may be appointed by the manufacturer, formulator or article producer established outside of Great Britain.

Human Cells and Biologics

Guidance to Consider:

<https://www.gov.uk/guidance/quality-and-safety-of-human-organs-tissues-and-cells-from-1-january-2021>

<https://www.hta.gov.uk/uk-transition-guidance>

Questions

would we have to register the cell lines with any organisation prior to import? The cell lines will be shipped in dry ice with a courier such as DHL, Fed-Ex.

From 1 January 2021, you will need to treat suppliers in the [European Economic Area](#) (EEA) as third country suppliers. This means if you import or export non-reproductive tissues or cells from or to the EEA you will need:

- an import or export licence
- for import, an import agreement with the supplier in the EEA
- You will have 6 months from 1 January 2021 to put these measures in place.

There will be no change to the import and export requirements for countries outside the EEA.

In line with the UK government’s commitment to unfettered access, there are no additional requirements to send or receive non-reproductive tissues or cells to or from Northern Ireland.

If you already have an import licence

If you already have an import licence because you currently import from countries outside the EEA, you will need to apply to update this. It will need to include the EEA countries you are importing from.

If you already have an export licence

If you already have an export licence because you currently export to countries outside the EEA, you do not need to do anything further.

Medical Devices Regulations

Guidance to consider:

<https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021>

<https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market-from-1-january-2021>

Questions

Can a UKCA sticker be applied to MHRA registered CE marked medical devices currently stocked here in the UK?

The UKCA mark can only be applied to a device if it is in compliance with the UK Medical Devices Regulations as set out in the [Medical Devices Regulations 2002](#) (SI 2002 No 618, as amended) (UK MDR 2002). UKCA mark requirements will continue to be based on the requirements of the relevant Annexes to the Directives listed below, which are given effect in UK law through the UK MDR 2002:

- [Directive 90/385/EEC](#) on active implantable medical devices (EU AIMDD)
- [Directive 93/42/EEC](#) on medical devices (EU MDD)
- [Directive 98/79/EC](#) on in vitro diagnostic medical devices (EU IVDD)

Where third party conformity assessment is required, a UK Approved Body will be needed. However, Class I device and general IVD (excluding those with a sterile or measuring function) manufacturers will be able to self-certify against the UKCA mark from 1 January 2021.

Will we HAVE to apply a UKCA sticker to all medical devices currently stocked in the UK from Jan 1st, i.e. devices that carry the CE mark?

No, we will continue to accept CE marked devices on the Great Britain market until 30 June 2023. This will apply to devices that have been CE marked under and fully conform with the following applicable EU legislation:

- [Directive 90/385/EEC](#) on active implantable medical devices (EU AIMDD)
- [Directive 93/42/EEC](#) on medical devices (EU MDD)
- [Directive 98/79/EC](#) on in vitro diagnostic medical devices (EU IVDD)
- [Regulation 2017/745](#) on medical devices (EU MDR)
- [Regulation 2017/746](#) on in vitro diagnostic medical devices (EU IVDR)

From 1 July 2023, new devices placed on the Great Britain market will need to conform with UKCA marking requirements.

If you currently CE mark your medical device on the basis of self-certification, you will be able to continue to do so after 1 January 2021 and place your device on the Great Britain market until 30 June 2023.

We import Class I devices from Italy - not own brand. Do we now have to register all these products with MHRA alongside our own brand products (made in UK)?

The manufacturer will require a UK responsible person to register products on their behalf. That can be the importer of the device or another person with a register place of import in the UK.

In cases where the Great Britain importer is not the UK Responsible Person, the importer will be required to inform the relevant UK Responsible Person of their intention to import a device. In such cases, the UK Responsible Person will be required to provide the MHRA with a list of device importers. We will provide further guidance in due course.

What about existing product in the UK ie already in the distribution chain? It may have a 5 year shelf life and not have a UKCA mark. Can it be sold as is/overlabeled/sticker added?

For a device is considered legally on the market it can remain on the market without further change to the packaging and labelling even if the regulations have changed unless a safety concern is raised and the MHRA recall the device from the market.

For Class 1 product from a UK manufacturer exporting to the EU, is there any transition period for having a EU Authorised Rep on packaging

Check with the Competent Authority where your authorised representative is based and the competent Authorities for where you sell your products. The EU has not issued EU wide guidance on this issue so it would be down to the discretion of the competent authority where the product is sold.

If you have medical devices already registered with the MHRA, will these be transferred to new system or will they have to be re-registered?

Products that are already registered with the MHRA will not require reregistration although the MHRA recommends checking the details of the registration are accurate for the end of the transition period.

do we need to put UKCA and or CE mark on both the label on the product and on the packaging.

In most cases, you must apply the UKCA marking to the product itself or to the packaging. In some cases, it may be placed on the manuals or on other supporting literature. This will vary depending on the specific regulations that apply to the product.

The following general rules apply:

- UKCA markings must only be placed on a product by you as the manufacturer or your authorised representative (where allowed for in the relevant legislation)
- when attaching the UKCA marking, you take full responsibility for your product's conformity with the requirements of the relevant legislation
- you must only use the UKCA marking to show product conformity with the relevant UK legislation
- you must not place any marking or sign that may misconstrue the meaning or form of the UKCA marking to third parties
- you must not attach other markings on the product which affect the visibility, legibility or meaning of the UKCA marking
- the UKCA marking cannot be placed on products unless there is a specific requirement to do so in the legislation

When using the UKCA marking you must make sure that:

- if you reduce or enlarge the size of your marking, the letters forming the UKCA marking must be in proportion to the version set out below
- the UKCA marking is at least 5mm in height – unless a different minimum dimension is specified in the relevant legislation
- the UKCA marking is easily visible, legible

What's the best time to register with MHRA? We currently only have the Prototype, have not got the CE mark yet?

You must register with the MHRA after your product has undergone UKCA or CE certification by the relevant conformity assessment body in the UK or EU (or has been self-certified where applicable) before placing the product on the market.

Is the EU AR for customs clearance only? Will authorised rep have to be added for sale to Europe on primary packaging as well as unit of sale - or is there a transition period.

A European Authorised Representative provides a point of contact between a non-European medical device manufacturer and the national Competent Authorities and Notified Bodies.

The name and address of the Authorised Representative must be included on your labelling, outer packaging or the instructions for use. You must also use the EU AR symbol as designated in EN ISO 15223-1:2016.

Under the new MDR (EU) 2017/745 Authorised Representatives have greater responsibilities and take on significantly more risk and liabilities, therefore you can expect your representative to scrutinise your documentation more thoroughly.

Will a product destined for the UK from a European Manufacturer have to carry the UKCA mark for three of our countries and then have to show an ADDITIONAL CE UK(NI) mark if we intend to sell into Northern Ireland?

A CE marking will continue to be needed for devices placed on the Northern Ireland market and EU rules will need to be met.

If you currently CE mark your device on the basis of self-certification, you will be able to continue to do so from 1 January 2021 for the purposes of the Northern Ireland market.

From 1 January 2021, to place a CE marking on your device for circulation in both Northern Ireland and the EU, you must use an EU-recognised Notified Body to undertake any mandatory third-party conformity assessment. The results of conformity assessments carried out by UK Notified Bodies will not be recognised within the EU.

The CE UK(NI) mark is only needed if you are placing certain medical devices on the Northern Ireland market after the transition period; and your goods require mandatory third-party conformity assessment; and you are planning to use a [UK body](#) to carry out those conformity assessments after the transition period

For the IVD COVID detect device, do we have to do the clinical trial ? how many cilinical sample we need to do?

Please see the MHRA's guidance on COVID tests here:

<https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/for-industry-and-manufactures-covid-19-tests-and-testing-kits>

Is it only approved NBs from within the UK that will be able to issue UKCA certification, or will approved NB's from outside the UK be able to issue UKCA certification?

From 1 January 2021, the MHRA will be able to designate UK Approved Bodies to conduct assessments against the relevant requirements for the purpose of the UKCA mark.

Existing UK Notified Bodies with designations under the EU MDD, EU IVDD or EU AIMDD will have their designations rolled over automatically, without having to undergo a new designation process.

For the purposes of the Great Britain market, UK Approved Bodies will only be able to conduct conformity assessments in relation to the UKCA mark, for medical devices, active implantable medical devices and in vitro diagnostic medical devices under Parts II, III, and IV of the UK MDR 2002 (in the form in which they exist on 1 January 2021).

Designated bodies under UK Mutual Recognition Agreements on conformity assessment would also be able to issue UKCA certification.

The bill mentioned in the webinar – what state is this in? Has it been approved in UK government? What is the best way to track progress and/or know the estimated timeline(s)?

The Medicines and Medical Devices Bill can be monitored here:

<https://services.parliament.uk/bills/2019-21/medicinesandmedicaldevices.html>

The medical device under development will need to go into clinical trials. What are the relevant regulations for this?

Those wanting to conduct clinical investigations in the UK should continue to apply to the MHRA as they do now.

The MHRA will assess clinical investigations in accordance with EU Directive requirements. However, they will accept studies designed in line with the EU MDR/IVDR, including any documentation prepared according to the requirements of these regulations e.g. GSPR checklist. Existing guidance will continue to apply. <https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device>

General Business Queries

please can you define UK? Does that include Northern Ireland or not?

The four nations of Great Britain and Northern Ireland make up the United Kingdom: Scotland, Wales, England and Northern Ireland.

Are digital SaaS medical devices subject to tariffs and do they require an EORI number?

No. if there is no physical good being exported then tariffs and EORI numbers do not apply.

What's happening with Euratom and nuclear substances?

Please see the guidance below on the treatment of nuclear material from 1 January 2021:

- <https://www.gov.uk/guidance/importing-relevant-nuclear-materials-from-the-eu-from-1-january-2021-licensing-requirements>
- <https://www.gov.uk/guidance/exporting-nuclear-related-items-from-1-january-2021>
- <https://www.gov.uk/guidance/shipping-radioactive-waste-and-spent-fuel-from-1-january-2021>
- <https://www.gov.uk/guidance/shipping-radioactive-sources-between-the-uk-and-eu-from-1-january-2021>

Will there be tariff (changes) for import goods from China / India

From the 1 January 2021 the UK will have an independent tariff regime from the EU, the UK global [tariff](#). This apply to all countries unless you are making use of the preferential arrangements under a free trade agreement.

are responsible persons going to be required for cosmetic products?

Guidance on all goods regulated under the product safety and metrology regulations including cosmetics can be found here: <https://www.gov.uk/guidance/product-safety-and-metrology-from-1-january-2021-great-britain>